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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,809	03/30/2004	Jeffrey Hutterer		6034

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,809	HUTTERER, JEFFREY	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,12-20,26-29 and 32-44* is/are pending in the application.

4a) Of the above claim(s) *36-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12-20,26-29,32-35 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2009 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of June 23, 2009 made to the office action filed March 24, 2008. Claims 1-6, 12-20 and 26-29, and 32-44 are pending. Claims 1, 6, 27 and 29 are amended. Claims 43 and 44 are new. In a restriction filed October 31, 2007, Applicant elected claims 1-35, in which claims 36-40 were withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 1-6, 12-20, 26-35 and 41-42 as being unpatentable over Roberts et al., in view of Platt, McCadden, O'Kane et al., and Healthchemist, were found not persuasive, thus the rejection is upheld.

The amendments to the claims did not overcome the 35 USC 112, first paragraph rejection of claim 6, thus the rejection is upheld.

In light of the amendments to the claims and further consideration, the new 35 U.S.C. 112, first paragraph rejection and the modified 35 U.S.C. 103(a) rejection is below. The Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Particularly, the specification nor the examples require a specific a ratio between the corticosteroid and the antihistamine of *approximately 1:5*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 12-20, 26-29, 32-35 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,750,141), in view of Platt (WO 98/10647 A1), in view of McCadden (US 6,479,058 B1), in view of O'Kane et al. (The Physican and sports medicine, September 1999, vol. 27(9), pp. 1-14) in further view of Healthchemist (online pharmacy printout of Naphcon being sold).

Roberts et al. teach a method of topical and/or transdermal administration of a vaso-active agent administered in combination with a therapeutic agent which is useful in treatment of the dermis epidermis, wherein the therapeutic agent may be administered in a similar manner in combination with the vaso-active agent or may be administered separately so as to increase local perfusion and/or concentration of the therapeutic agent at the administration site of the vaso-active agent (see abstract and claim 1; addresses claims 1, 27, 43 and 44). The composition may also include a suitable vehicle or carrier (see column 6, lines 35-36) for delivery suitable for

preparations such as creams, aerosol sprays, solutions and gels (see column 8, lines 10-23; addresses claims 43 and 44). The topical administration can be used to cover administration to the nose, eye, ear, or any other body part accessible to local administration (see column 8, lines 10-23; addresses claims 43 and 44). Thus, eye solutions or nasal sprays can be used to apply the composition as disclosed in claims 43 and 44. Therapeutic agents include corticosteroids such as hydrocortisone and descamethasone, and antihistamines. (see column 6, lines 39, 40, 49, 53, 54 and 55; see column 6, line 52; addresses 1, 6, 20, 27, 29-34, 43 and 44). Suitable vasoconstrictors include naphazoline (i.e. decongestant) and phenylephrine hydrochloride (i.e. decongestant; see column 7, lines 33, 41, 42 and 43; addresses claims 1, 3-5, 14-19, 27, 43 and 44).

Roberts et al. does not teach pheniramine maleate, the amounts of the combination solution (claims 1, 2, 3, 4, 5, 13-19, 27, 28 and 43), the ratio of the corticosteroid cream and the antihistamine (claims 1, 6, 27 and 29-31), the amounts of the corticosteroid cream (claims 1, 13, 27, 43 and 44), specifically a 1% cream of hydrocortisone (claims 12, 26 and 35). Roberts et al. does not specifically teach eye drops (claim 43) or spraying the nasal spray for specifically one half second (claim 44).

Pratt teaches a topical preparation of an antihistaminic chemical compound and at least one hydrocortisone compound to treat various types of dermatitis (see abstract and title). The antihistamine can be pheniramine maleate (see page 7, line 19; claim 3).

The combination effectively treats dermatitis caused by a noxious agent or by an allergic reaction much quicker and with deep penetration and time release features making it more effective than either over-the-counter or prescription preparations (see page 6, second paragraph in its entirety.)

McCadden teach a composition for the topical treatment of skin eruptions from psoriasis (see title and column 1, lines 19 and 20) comprising a corticosteroid of appropriate potency for the condition being treated (see column 2, lines 50-53) in the form of a cream (see column 2, last line). Low potency steroids are generally preferred in view of certain disadvantages of high potency steroids such as hydrocortisone, most preferably from about 0.5 to about 2.5% (see column 4, lines 63-65 and column 5, lines 8-10). The composition is applied topically to the involved area until it has healed (see column 10, lines 11-12).

O'Kane et al. teach topical vasoconstrictors for the treatment of allergic conjunctivitis including the application of 1 drop of a 0.1% solution of Naphazoline HCl and pheniramine maleate, also known as Naphcon-A (see page 5, table 2, see page 6, topical vasconstrictors, third entry).

Healthchemist teaches that the Naphcon-A product comprisings 0.25 mg/ml of naphazoline hydrochloride and 3 mg/ml of pheniramine maleate (see active ingredients).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. and the combination of pheniramine maleate with either naphazoline HCl or phenylephrine HCl because of the following teachings: (1) Pratt teaches a topical preparation of an antihistaminic chemical compound and at least one hydrocortisone compound to treat various types of dermatitis (see abstract and title).; (2) Pratt teaches that the combination effectively treats dermatitis caused by a noxious agent or by an allergic reaction much quicker and with deep penetration and time release features making it more effective than either over-the-counter or prescription preparations (see page 6, second paragraph in its entirety); and (3) "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Platt and the specific 1% cream of hydrocortisone (claims 12, 26 and 35)

because McCadden teach a composition for the topical treatment of skin eruptions from psoriasis (see title and column 1, lines 19 and 20) comprising from about 0.5 to about 2.5% of the hydrocortisone cream (see column 2, lines 50-53; column 2, last line; column 4, lines 63-65 and column 5, lines 8-10). Thus, psoriasis is effectively treated with a 1% hydrocortisone cream. Therefore, one would be motivated to use this concentration of hydrocortisone for the method of Roberts et al. in view of Platt.

In regards to the actual amount of cream applied as disclosed in applicant's claims 1, 13, 27, 43 and 44, it would be obvious to apply approximately 0.05 grams to approximately 0.2 grams or approximately 0.03 grams and approximately 0.3 grams, because McCadden teaches that the hydrocortisone composition is applied topically to the involved area until it has healed (see column 10, lines 11-12). Thus, the amount to cover the area can comprise approximately 0.05 grams to approximately 0.2 grams, depending on the size of the area to be treated.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Platt and the amounts of the combination solution (claims 1, 2, 3, 4, 5, 13-19, 27, 28 and 43), or the time to spraying the affected area with the combination solution (claim 44) because of the following teachings: (1) O'Kane et al. teach topical vasoconstrictors for the treatment of allergic conjunctivitis including the application of 1 drop of a 0.1% solution of Naphazoline HCl and pheniramine maleate, also known as

Naphcon-A (see page 5, table 2, see page 6, topical vasconstrictors, third entry); (2) Healthchemist teaches that the Naphcon-A product comprisings 0.25 mg/ml of naphazoline hydrochloride and 3 mg/ml of pheniramine maleate (see active ingredients); and (3) It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003). Thus, a combination of a decongestant and an antihistamine is known in the applicant's disclosed ratios and applied in the amounts of a volume of at least approximately 0.02 ml (1 to 2 drops). Further, Roberts teaches that the solutions can be applied by spray. One skilled in the art can determine the amount needed to treat the affected area.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Platt and the ratio of the corticosteroid cream and the antihistamine as disclosed in claims 1, 6, 27 and 29-31 because one skilled in the art would be able to determine the effective amount of each component through standard tests. The motivation is to provide effective treatment for the dermatitis. It is noted that "[W]here

the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

In regards to the method relieving or alleviating symptoms within approximately two to four minutes, or that the symptoms last for approximately two to five hours, the Examiner renders the above limitations obvious over the above references. Roberts et al. teach a method useful in treatment of the dermis epidermis in which the method can be adopted to prolonged periods of 2-12 hours (see column 7, lines 9-10). Since all references teach a method of treatment, it is viewed by the Examiner that the symptoms of the dermatitis is relieved or/and alleviated. In regards to the time factor, both Roberts et al. and Pratt describe that the methods used increase the effectiveness time by increasing penetration. Thus, one skilled in the art would anticipate that the combination would produce shorter relief times than the drugs individually as stated by Pratt (see page 6, second paragraph in its entirety.)

In regards to the method using an eye drop solution (claim 43), the Examiner finds this limitation obvious since Roberts et al. teach that the composition can be applied to the eyes and as a solution (see column 8, lines 10-23; and column 8, lines 10-23.) It is well known in the art that eye drops are a common delivery system to apply solutions to eyes.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that Roberts is an ineffective reference for the following reasons: 1) it is not apparent that the teachings of Roberts can be applied with Platt to generate relief of the dermatological symptoms in the present invention using the particular compounds; and 2) one would need to carry out undue further experimentation to combine Roberts and Platt to come to the current invention. Further, the Applicant's continue to argue that Roberts has contradictions that question the credibility or Roberts with respect to any kind of vas-active agent. The teachings of Roberts is vague and depend so much on future experimentation with particular therapeutic agents, particular vaso-active agents and particular depths of concentrations useful in particular medical conditions, all left unspecified by Roberts.

The Examiner respectfully disagrees, and notes that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In regards to the dermatological symptoms being treated, Roberts et al. teach a method of topical and/or transdermal administration of a vaso-active agent administered in combination with a therapeutic agent which is useful in treatment of the dermis epidermis, wherein the therapeutic agent may be administered in a similar manner in combination with the vaso-active agent or may be administered separately so as to increase local perfusion and/or concentration of the therapeutic agent at the administration site of the vaso-active agent (see abstract and claim 1). Thus, Roberts et al. teaches a method of

treating dermatological conditions not known to be caused by a virus or bacteria as claimed. The Examiner disagrees that extensive and undue experimentation would have to be performed to carry arrive to the present invention. The Roberts reference teaches that the corticosteroid is applied separately from the antihistamine and carriers can be used (see abstract; claim 1; column 6, lines 35-36). Platt provides the teaching of why one would combine a corticosteroid with a antihistamine, particularly, the combination of pheniramine maleate with either naphazoline HCl or phenylephrine HCl. Further, Platt uses the hydrocortisone as a carrier (see page 8, second paragraph) when combined with the antihistamine, with examples of ratios (see page 8, paragraph 3).

The specific method steps claimed are obviously taught by McCadden, O'Kane and Healthchemist. As disclosed in the rejection above, it would be obvious to apply approximately 0.05 grams to approximately 0.2 grams because McCadden teaches that the hydrocortisone composition is applied topically to the involved area until it has healed (see column 10, lines 11-12). Thus, the amount to cover the area can comprise approximately 0.05 grams to approximately 0.2 grams, depending on the size of the area to be treated. Further, one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Platt and the amounts of the combination solution (claims 1, 2, 3, 4, 5, 13-19, 27 and 28) because of the following teachings: (1) O'Kane et al. teach topical vasoconstrictors for the treatment of allergic conjunctivitis including the application of 1 drop of a 0.1% solution of Naphazoline HCl and

pheniramine maleate, also known as Naphcon-A (see page 5, table 2, see page 6, topical vasconstrictors, third entry); (2) Healthchemist teaches that the Naphcon-A product comprisings 0.25 mg/ml of naphazoline hydrochloride and 3 mg/ml of pheniramine maleate (see active ingredients); and (3) It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003). Thus, a combination of a decongestant and an antihistamine is known in the applicant's disclosed ratios and applied in the amounts of a volume of at least approximately 0.02 ml (1 to 2 drops). One skilled in the art can determine the amount needed to treat the affected area.

In regards to the teachings of Robert and the vasoconstrictor or vasodilator, Robert teaches the combination of a vaso-active agent (see claim 1) which can be a vasodilator or vasoconstrictor. Both independently act as a vaso-active agent that facilitates faster delivery of the therapeutic agent (see column 6, lines 7-31). Upon knowing the above, it is within the skill of the art to perform the routine experimentation

to find ranges and amounts of the vaso-active agent and the therapeutic agent based on what is already known in the art. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kendra D Carter/
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
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